

EXHIBIT A
(Part One)

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

)
) Master File
) No. 01-CV-10861 (MDL 1430)
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THIS DOCUMENT RELATES TO
ALL ACTIONS

SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement and Release (the "Class Agreement") is submitted pursuant to Rule 23 of the Federal Rules of Civil Procedure. Subject to the approval of the Settlement Court, this Class Agreement is entered into between and among (i) the Class Representatives on behalf of themselves and the Lupron® Purchaser Class (the "Plaintiffs") and (ii) Defendants TAP Pharmaceutical Products Inc. ("TAP"), Abbott Laboratories ("Abbott"), and Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.) ("Takeda") (collectively the "Defendants"), by and through their respective counsel.

WHEREAS, there is pending in the United States District Court for the District of Massachusetts a consolidated and coordinated proceeding comprised of actions, including the above-captioned actions, in which the Plaintiffs have alleged, *inter alia*, that some or all Defendants have engaged in improper and fraudulent marketing, pricing, and sales of the prescription drug Lupron®.

WHEREAS, Defendants have asserted a number of defenses to the claims by the Plaintiffs;

WHEREAS, the Plaintiffs and Defendants agree that this Class Agreement shall not be deemed or construed to be an admission or evidence of any violation of any statute or law or of any liability or wrongdoing by Defendants or of the truth of any of the claims or allegations alleged in any Lupron® Pricing Litigation or a waiver of any defenses thereto;

WHEREAS, Class Settlement Counsel have concluded, after extensive discovery and investigation of the facts and after carefully considering the circumstances of the class action, including the claims asserted in the complaint filed in the class action and the possible legal and factual defenses thereto, that it would be in the best interests of the Plaintiffs to enter into this Class Agreement in order to avoid the uncertainties of litigation and to assure that the benefits reflected herein are obtained for the Plaintiffs; and, further, that Class Settlement Counsel consider the settlement set forth herein to be fair, reasonable and adequate and in the best interests of the Plaintiffs;

WHEREAS, the Lupron® Purchaser Class is comprised of (i) third-party payor ("TPP") purchasers, and (ii) individual consumers ("Consumers"), who paid for all or part of the cost of Lupron® prescribed, provided or administered in the United States during the Class Period;

WHEREAS, a group of health insurance companies and health plans ("Settling Health Plans," "SHPs," or "SHP Group"), who have represented that the SHPs, in the aggregate, provide or administer prescription drug and health benefits to at least seventy percent (70%) of the 197,869,000 covered lives privately insured in the United States (based on U.S. Census data published

December 31, 2003), have executed a separate settlement agreement with Defendants (the "SHP Agreement");

WHEREAS, the settlement between the SHP Group and Defendants requires a coordination of the claims administration process for the Lupron® Purchaser Class and the SHP Group;

WHEREAS, Defendants, through their counsel, Plaintiffs, through Class Settlement Counsel, and the SHP Group, through SHP Group Counsel, after months of vigorous, arms-length negotiations, have conditionally agreed to payment by Defendant TAP of one hundred-fifty million dollars (\$150,000,000) to settle the Lupron® MDL Actions and all claims of the Plaintiffs and the SHP Group, of which amount ninety-five million dollars (\$95,000,000) will be allocated to the Plaintiffs and fifty-five million dollars (\$55,000,000) will be allocated to the SHP Group as provided in this Class Agreement and the SHP Agreement;

WHEREAS, additional class counsel appointed by Class Settlement Counsel engaged in vigorous arms-length negotiations to apportion the ninety-five million dollars (\$95,000,000) allocated to the Plaintiffs (the "Class Settlement Fund") between Consumers and TPPs, and reached agreement to apportion forty million dollars (\$40,000,000) to Consumer Class Members (the "Consumer Settlement Pool") and fifty-five million dollars (\$55,000,000) to TPP Class Members (the "TPP Settlement Pool");

WHEREAS, the Settlement Court has found that Takeda is not subject to personal jurisdiction as to Lupron®-related actions filed in Massachusetts,

Alabama, and Minnesota, and Takeda does not by virtue of this Class Agreement concede that it had or has minimum contacts with any state sufficient to subject it to personal jurisdiction in that state;

WHEREAS, Defendants, despite their belief that they have good defenses to the claims asserted against them in the Lupron® MDL Actions and in other Lupron® Pricing Litigation, have nevertheless agreed to enter into this Class Agreement and the SHP Agreement to reduce and avoid further expense, inconvenience, and the distraction of burdensome and protracted litigation, and thereby to resolve this controversy;

NOW, THEREFORE, it is agreed by and between the undersigned on behalf of Defendants and the Plaintiffs that any and all claims made or that could have been made against Defendants by Plaintiffs in the Lupron® MDL Actions or any other Lupron® Pricing Litigation be settled, compromised and dismissed on the merits and with prejudice and, except as hereafter provided, without costs as to Plaintiffs or Defendants, subject to the approval of the Settlement Court, on the following terms and conditions:

1. Lupron® Purchaser Class Definition. Subject to the Settlement Court's approval, and the conditions of Paragraphs 23 and 24, the undersigned agree and consent to the certification of the following settlement class (the "Lupron® Purchaser Class") in the Lupron® MDL Actions:

All individual persons or entities who, during the Class Period, made Lupron® Purchases. Excluded from the class are the Settling Health Plans; Defendants, their respective present and former, direct and indirect, parents, subsidiaries, divisions, partners and affiliates; and the United States government, its officers, agents,

agencies and departments, and all other government entities' claims, to the extent that they previously released their claims pursuant to the 2001 Settlement Agreement and Release resolving the matter of *United States of America v. TAP Pharmaceutical Products, Inc.* (D. Mass.) and related litigation.

2. General Definitions. As used in this Class Agreement, the following terms shall have the indicated meanings:

(a) "Class Period" means January 1, 1985 through the end of the Settlement Notice period established by the Settlement Court, which date shall be no earlier than December 31, 2004.

(b) "Consumer" means any person falling within the definition of the Lupron® Purchaser Class who is a natural person and not a TPP. "Consumer" includes living persons as well as the executors, heirs, administrators, trustees, or other authorized representatives of deceased persons.

(c) "Consumer Class Members" means Consumers who are not Class Opt-Outs.

(d) "Consumer Settlement Pool" means forty million dollars (\$40,000,000) from the Class Settlement Fund, which amount shall be segregated into an account for Consumer Class Members as described in Paragraph 9, plus all interest or other income that accrues thereon.

(e) "Net Consumer Settlement Pool" means the balance of the Consumer Settlement Pool after deducting fees, expenses and costs, and is more fully discussed in Paragraph 17.

(f) "Authorized Consumer Claimant" means a Consumer Class Member who submits a Proof of Claim that is accepted in whole or in part by the Claims Administrator.

(g) "Court" or "Settlement Court" means the Honorable Richard G. Stearns of the United States District Court for the District of Massachusetts, or if Judge Stearns is not available, another judge from the United States District Court for the District of Massachusetts who will be designated by Judge Stearns or who is appointed, or any subsequent court before which Defendants' Counsel and Class Settlement Counsel agree to settle the claims of the Lupron® Purchaser Class.

(h) "Class Member" means any person or entity falling within the definition of the Lupron® Purchaser Class other than any Class Opt-Outs.

(i) "Class Counsel" means all attorneys and law firms that have filed a general appearance on behalf of a putative class of plaintiffs in any of the Lupron® MDL Actions as of November 1, 2004.

(j) "Class Settlement Counsel" means the law firms of SPECTOR ROSEMAN & KODROFF; COHEN, MILSTEIN, HAUSFELD & TOLL, P.L.L.C.; LIEFF

CABRASER HEIMANN & BERNSTEIN, LLP; FOOTE MEYERS MIELKE & FLOWERS; and HAGENS BERMAN LLP.

(k) "Class Opt-Out" means any person or entity falling within the definition of the Lupron® Purchaser Class who timely and validly submits a request for exclusion from the Lupron® Purchaser Class in accordance with the procedures set forth in the Settlement Notice. A Class Opt-Out that is a Consumer is also referred to as a "Consumer Opt-Out." A Class Opt-Out that is a TPP is also referred to as a "TPP Opt-Out."

(l) "Class Representatives" means the named plaintiffs who have asserted claims on behalf of themselves and a putative class in the Lupron® MDL Actions.

(m) "Claims Administrator" means Complete Claim Solutions, Inc.

(n) "Claim Documentation" means the materials required for submission of a claim pursuant to this Class Agreement. The Claim Documentation is set forth in Exhibit F.

(o) "Defendants" means TAP Pharmaceutical Products Inc., Abbott Laboratories, and Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.).

(p) "Defendants' Counsel" means the law firms of JONES DAY, WINSTON & STRAWN LLP, and JENNER & BLOCK LLP.

(q) "Effective Date" has the meaning ascribed in Paragraph 7 of this Class Agreement.

(r) "Escrow Account" means the account established pursuant to Paragraph 9 of this Class Agreement.

(s) "Lupron®" means Lupron® and Lupron Depot®.

(t) "Lupron® Purchases" means payment or reimbursement, direct or indirect, for all or part of the cost of Lupron® prescribed, provided or administered in the United States; including, but not limited to, the payment or partial payment for or reimbursement of Lupron® to any doctor, medical practice, pharmacy or any other health care provider, or the payment of a co-insurance amount, deductible amount, flat payment amount or co-pay amount for Lupron® pursuant to a Medicare co-insurance obligation, an insurance agreement, or other health care plan. "Lupron® Purchases" includes, but is not limited to, transactions where the cost, reimbursement amount or price of the Lupron® to the Consumer Class Member, TPP Class Member, SHP Group Member, or any doctor, pharmacy or other health care provider, was based in any part on the Average Wholesale Price ("AWP") or any other price of Lupron® or any other product as published by Redbook, Medispan, or any similar

publication. "Lupron® Purchases" does not include purchases of Lupron® for resale purposes.

(u) "Lupron® MDL Actions" means the consolidated claims of the Lupron® Purchaser Class and SHP Group in *In Re Lupron® Marketing and Sales Practice Litigation*, Case No. 01-CV-10861 (D. Mass.) (MDL 1430).

(v) "Lupron® Pricing Litigation" means the Lupron® MDL Actions and all other pending litigation in any federal or state court asserting claims against the Defendants or any of them in any way similar to the Released Claims.

(w) "Plaintiffs" means the Class Representatives together with all putative members of the Lupron® Purchaser Class.

(x) "Releasees" means TAP Pharmaceutical Products Inc. (formerly TAP Holdings Inc.); TAP Pharmaceuticals Inc.; TAP Finance Inc.; Abbott Laboratories; Takeda Pharmaceutical Company Limited (formerly Takeda Chemical Industries, Ltd.); Takeda Pharmaceuticals North America, Inc.; Takeda America Holdings, Inc.; and each of their respective past, present and future, direct and indirect, parents, subsidiaries, divisions, partners and affiliates, and their respective past, present and future stockholders, officers, directors, employees, managers, sales representatives, agents, attorneys, insurers, and any other persons or entities who are alleged to have been involved in the distribution, dispensing and prescription of Lupron® and any of

their legal representatives, and the predecessors, heirs, successors, executors, trustees, administrators and assigns of each of the foregoing. As used in this Paragraph, "affiliates" means entities controlling, controlled by or under common control with a Releasee.

(y) "Released Claims" means any and all claims, demands, actions, suits, causes of action, damages whenever incurred, liabilities of any nature whatsoever, including costs, expenses, penalties and attorneys' fees, known or unknown, suspected or unsuspected, in law or equity, that any Releasor who has not timely excluded themselves from the Lupron® Purchaser Class, whether or not they object to the settlement and whether or not they make a claim upon or participate in the Class Settlement Fund, ever had, now has, or hereafter can, shall or may have, directly, representatively, derivatively or in any capacity, arising out of any conduct, events or transactions alleged or that could have been alleged in any litigation relating to the marketing, sale, cost, pricing or purchase of Lupron®. "Released Claims" specifically includes, but is not limited to, all claims against any person or entity relating to Lupron® transactions where the cost, reimbursement amount or price of the Lupron® to the Consumer Class Member, TPP Class Member, SHP Group Member, or any doctor, pharmacy or other health care provider, was based in any part on the Average Wholesale Price ("AWP") or any other price of Lupron® or any other product as published by Redbook, Medispan, or any similar publication. All Releasors covenant and agree that, after the Effective Date of this Class Agreement, they shall not seek to establish liability based, in whole or in part,

on any of the Released Claims. "Released Claims" shall not include claims arising out of this Class Agreement or claims between members of the Lupron® Purchaser Class and any of the Releasees concerning product liability or personal physical injury.

(z) "Releasors" means (1) all Consumer Class Members, as well as their successors, assigns, heirs, executors, trustees, and administrators, and (2) all TPP Class Members and each TPP Class Member's respective present and former, direct and indirect, parents, subsidiaries, divisions, partners and affiliates, their respective present and former stockholders, officers, directors, employees, managers, agents, attorneys and any of their legal representatives, any future operating entities created and controlled by a TPP Class Member (not including any successor of a TPP Opt-Out), and any predecessors, successors, heirs, executors, trustees, administrators and assigns of each of the foregoing, all in their capacities as such, and any entities or persons (including, to the extent that a TPP Class Member administered their Lupron® Purchases, all entities for which any TPP Class Member provides or provided administrative services) on whose behalf the TPP Class Member is authorized to act. All Released Claims are forever discharged, and such claims cannot be asserted by any of Releasors' future, direct and indirect, parents, subsidiaries, divisions, partners and affiliates, their respective future stockholders, officers, directors, employees, managers, agents, attorneys and any of their legal representatives, or any successors, heirs, executors, trustees, administrators, or assigns of each of the foregoing. As used in this Paragraph, "affiliates"

means entities controlling, controlled by or under common control with a Releasor.

(aa) "Settlement Amount" means one hundred fifty million dollars (\$150,000,000), which is to be paid by TAP in full and final satisfaction of all Released Claims held by any Consumer Class Member, TPP Class Member or SHP Group Member. The Settlement Amount is inclusive of any payments for reasonable attorneys' fees and costs of any kind, including all costs associated with Settlement Notice and claims and escrow administration.

(bb) "Class Settlement Fund" means ninety-five million dollars (\$95,000,000), which represents the Settlement Amount minus the SHP Group Initial Payment. TAP shall transfer the Class Settlement Fund, and it shall be allocated into the "TPP Settlement Pool" and the "Consumer Settlement Pool" as provided in Paragraph 9.

(cc) "Settlement Notice" means the Notice of Pendency and Proposed Settlement of Class Action, Motion for Attorneys' Fees and Settlement Hearing substantially in the form annexed hereto as Attachment 1 to Exhibit A and the Summary Notice annexed hereto as Attachment 2 to Exhibit A.

(dd) "SHP Group," "Settling Health Plans," or "SHPs" means all of the entities identified in Exhibit C to this Class Agreement (the "SHP Group Members"), together with all self-funded healthcare plans and/or entities ("SFPs") for which one or more SHP Group Members provides or provided

prescription drug or health benefit services through administrative services-only contracts or as a third-party administrator and on whose behalf the SHP Group Member warrants it is authorized to make a claim, to the extent that such SHP Group Member administered such SFP's Lupron® Purchases. Such SFPs will be identified in the Claim Documentation submitted by the SHP Group pursuant to Paragraph 12 of this Class Agreement and Paragraph 4 of the SHP Agreement. Additional members may be added to the SHP Group as provided in Paragraph 17 of the SHP Agreement.

(ee) "SHP Group Counsel" means the law firms of DEWEY BALLANTINE LLP; SCHNADER HARRISON SEGAL & LEWIS LLP; LOWEY DANNENBERG BEMPORAD & SELINGER P.C.; SUSMAN & GODFREY, LLP; and RAWLINGS & ASSOCIATES, P.L.L.C..

(ff) "SHP Group Recognized Claim Percentage" or "SHPRCP" means the total amount of claims by all SHP Group Members that are allowed by the Claims Administrator divided by the total allowed claims of (a) all Authorized TPP Claimants, (b) all members of the SHP Group, and (c) all TPP Opt-Outs for which TAP receives a refund from the TPP Settlement Pool pursuant to Paragraph 11 of this Class Agreement.

(gg) "SHP Group Initial Payment" means fifty-five million dollars (\$55,000,000) from the Settlement Amount.

(hh) "SHP Group Escrow" means fifteen million dollars (\$15,000,000) from the SHP Group Initial Payment.

(ii) "SHP Over/Underage" means the SHPRCP less fifty percent (50%). For example, if the SHPRCP is 60%, then the SHP Over/Underage would be a positive 10%. If the SHPRCP is 42%, then the SHP Over/Underage would be a negative 8%.

(jj) "SHP Group Reversion Amount" means an amount calculated after all TPP claims have been processed and the total allowed claim amounts for all Authorized TPP Claimants and the SHP Group have been determined by the Claims Administrator. The SHP Group Reversion Amount is calculated differently depending on whether the SHP Over/Underage is positive or negative.

If the SHP Over/Underage is positive, then the SHP Group Reversion Amount means the amount determined by the following calculation: $\text{SHP Over/Underage} \times [(\$110,000,000 - \text{TAP Refund}) \times (1 - \text{TPP Class Fees \& Expenses} / \$55,000,000)]$. "TAP Refund" is defined in Paragraph 2(kk). "TPP Class Fees & Expenses" is defined in Paragraph 2(nn) below.

If the SHP Over/Underage is negative, the SHP Group Reversion Amount means the amount determined by the following calculation: $(-\text{SHP Over/Underage}) \times \$110,000,000$. In this formula, the "(-SHP Over/Underage)" makes the negative SHP Over/Underage a positive percentage. The SHP Group Reversion Amount calculated pursuant to this formula can be no more than

the value of the SHP Group Escrow as of the date of payment of the SHP Group Reversion Amount.

By way of illustration, Exhibit E to this Class Agreement sets forth sample calculations of the SHP Group Reversion Amount.

(kk) "TAP Refund" means the refund owed to TAP as a result of any TPP Opt-Outs, and is further described in Paragraph 11.

(ll) "Third-Party Payor" or "TPP" means a private or governmental entity that was at risk by contract to pay all or part of the cost of Lupron® prescribed, provided or administered in the United States for individual beneficiaries of the TPP's prescription drug or health coverage. Excluded are Defendants, their respective present and former, direct and indirect, parents, subsidiaries, divisions, partners and affiliates; and the United States, its officers, agents, agencies and departments, and all other government entities' claims, to the extent that they previously released their claims pursuant to the 2001 Settlement Agreement and Release resolving the matter of *United States of America v. TAP Pharmaceutical Products, Inc.* (D.Mass.) and related litigation. A claim may be made pursuant to this Class Agreement on behalf of a TPP Class Member by an agent thereof, including the third-party administrator of the TPP Class Member's prescription drug or health benefit plan, if the TPP Class Member authorizes the agent to make such a claim.

(mm) "TPP Class Members" means TPPs falling within the definition of the Lupron® Purchaser Class, excluding any Class Opt-Outs.

(nn) "TPP Class Fees and Expenses" means the sum of (1) the lesser of (a) the total attorney fee award granted by the Settlement Court pursuant to Paragraph 13 of this Class Agreement times the TPP Class Formula (defined below) or (b) thirteen million seven hundred fifty thousand dollars (\$13,750,000); plus (2) all litigation-related expenses and costs approved by the Settlement Court pursuant to Paragraph 13 of this Class Agreement times the TPP Class Formula. The TPP Class Formula equals $(\text{TPP Settlement Pool} - \text{TAP Refund}) / ((\text{TPP Settlement Pool} - \text{TAP Refund}) + \text{Consumer Settlement Pool})$.

(oo) "TPP Settlement Pool" means fifty-five million dollars (\$55,000,000) from the Class Settlement Fund, which amount shall be segregated into an account as provided in Paragraph 9, plus all interest or other income that accrues thereon.

(pp) "Net TPP Settlement Pool" means the TPP Settlement Pool after the payment of fees, expenses, costs, the SHP Group Reversion Amount, and the TAP Refund, if any.

(qq) "Authorized TPP Claimant" means a TPP Class Member who submits a Proof of Claim that is accepted in whole or in part by the Claims Administrator. The Claims Administrator shall not authorize any claims made by TPP Class Members on behalf of Defendants, their respective present and former, direct and indirect, parents, subsidiaries, partners and affiliates, or on behalf of any government entity to the extent that such government entity's

claims have been released or are otherwise excluded pursuant to Paragraph 1 of this Class Agreement.

(rr) "United States" means the United States of America including its states, commonwealths, territories and possessions.

3. Reasonable Best Efforts to Effectuate This Settlement. The parties and their counsel agree to use their reasonable best efforts, including all steps and efforts contemplated by this Class Agreement and any other steps and efforts that may be necessary or appropriate, including, to the extent applicable, the steps and efforts contemplated by the SHP Agreement, by order of the Settlement Court or otherwise, to carry out the terms of this Class Agreement.

4. Motion for Preliminary Approval. Concurrent with or shortly following the submission of this Class Agreement for consideration by the Settlement Court, and in no event later than November 12, 2004, Class Settlement Counsel shall submit to the Settlement Court a motion for preliminary approval of the settlement set forth in this Class Agreement, and requesting entry of a Preliminary Approval Order substantially in the form annexed hereto as Exhibit A.

5. Notice to Class. In the event the Settlement Court preliminarily approves the settlement set forth in this Class Agreement, Class Settlement Counsel shall, in accordance with Rule 23 of the Federal Rules of Civil